Northeastern University
Human Subject Research Protection

Guidance: Reliance Agreements

To help reduce the administrative burden with duplicative reviews and manage the complexity of multi-site research, reliance agreements may be established. This guide provides information for Northeastern University (NU) researchers who are collaborating with co-investigators/research team members who are affiliated with other institutions or are independent investigators.

Northeastern applies the same principles detailed in the federal regulations, CFR Title 45, Part 46 regardless of funding source. Therefore, the reliance agreement processes extend to research studies with no external funding.

Definitions

Engaged in Research: The Office for Human Research Protections (OHRP) developed guidance on when an institution is considered to be engaged in human subject research. Essentially, OHRP considers an institution "engaged" in non-exempt human subjects research when its employees or agents, for the purposes of a research project, obtain:

a. Data about the subjects of the research through intervention or interaction with them;
b. Identifiable private information about the subjects of the research;
c. the informed consent of human subjects.

Reliance Agreement: a document signed by two or more institutions engaged in human subject's research that permit one or more institutions to cede review to or rely on another IRB. Reliance agreements may cover single studies, categories of studies, or all human subjects research conducted under an organization's Federalwide Assurance (FWA).

The reliance agreement documents the respective authorities, responsibilities, and communication between the organization/institution conducting the regulatory review of human subject research activities and the institution(s) relying on the reviewing IRB. Therefore, **even when** Northeastern has ceded IRB review to a central/single IRB, submission to the NU Human Research Protection Program (HRPP) is required so that the HRPP can maintain its responsibilities under the reliance agreement.

Types of reliance agreements

Institutional Authorization Agreement (IAA): a formal, written agreement in which the reviewing IRB agrees to serve as the IRB of record for a relying institution. Agreements are generally used to cover a single research study, categories of research studies, or all human subjects research under an organizations FWA.

Individual Investigator Agreement (IIA): an agreement is when one institution agrees to serve as the IRB of record for a non-NU investigator who's collaborating on the research study and is not affiliated with an institution with its own IRB.

Note: Northeastern will not engage in reliance agreements with institutions that do not hold an FWA. External investigator agreements or separate IRB oversight (i.e. commercial IRB) may be sought in those cases.

Single IRB (sIRB)

Effective January 2018, the NIH requires use of a sIRB for the review of NIH-funded multisite studies where each site will conduct the same protocol involving non-exempt human subjects research.

The Department of Health & Human Services (DHHS) implemented a similar policy in January 2020 for research studies conducted or supported by HHS agencies.

SMART IRB

SMART IRB[1] is an online reliance system that aids in cooperative research between institutions.

Northeastern is a participating institution in SMART IRB. It is NU's preference to use the SMART IRB agreement as the basis of reliance for all studies where NU relies on an external IRB or serve as the IRB of record for an institution.

Process

To request for Northeastern to rely on another IRB for oversight of a study submit the following to IRBReliance@northeastern.edu:

- Northeastern's Relying Intake Form.
- IRB approval from the external IRB, approved protocol and consent documents
- Prepare a research team form listing all NU-affiliated investigators who will be engaged in human subjects research activities on the protocol, including their CITI training certificates.
- Please have information provided by the reviewing IRB pertaining to how they document reliance.

To Request for NU to provide IRB oversight for another institution, please submit the following to IRBReliance@northeastern.edu:

- NU IRB of record intake form. Complete one intake form per institution
- NU IRB application and if applicable the consent form revised with information on the roles and responsibilities your collaborators
- Confirmation if the relying site investigator has initiated the reliance process with their home institution's IRB office before submitting the form

[1] Streamlined, Multisite, Accelerated Resources for Trials (IRB Reliance platform)

Using the SMART IRB online reliance system

The request is typically initiated by the lead study team whose IRB will be serving as the IRB of Record for all sites. Each person requiring access to the online reliance system will need to submit a separate request for access to the system. If you've requested access and haven't received confirmation within a week please contact IRBReview@northeastern.edu.

Reliance decisions in SMART IRB apply only to the determination of reliance and do not reflect IRB approval for the research project itself. Approval for each collaborating institution must be obtained from the overall IRB of Record prior to beginning research with that site or its collaborators.

SMART IRB Letter of Acknowledgement (LOA)

The SMART IRB Letter of Acknowledgement (LOA) allows research teams to utilize a paper or electronic document to execute reliance agreements under the terms of the SMART IRB master reliance agreement. This document follows a similar process as other types of reliance agreements. Each site will need to sign a separate LOA with the proposed IRB of Record.

International Sites

Northeastern is not able to serve as IRB of record for sites or personnel in countries outside the US. Instead, review and approval by a review board or ethics committee in the country in which the research will be conducted should be obtained.

If a collaborative project is determined exempt from IRB review at another institution, will I still need to seek review at Northeastern?

Yes. Northeastern does not cede review for exempt research. Northeastern researchers must submit an exempt application and obtain an official exemption determination from Northeastern.

If a project is determined exempt from IRB review at Northeastern does exemption cover my collaborators at other institutions?

No. External collaborators will need to complete whatever review is required by their respective organizations/institutions.

Indemnification Language

Any reliance agreement containing indemnification language must be referred to the Office of General Counsel for review and approval prior to finalizing the agreement.

Local study team responsibilities

Investigators should be aware that reliance arrangements frequently require additional work on the part of the local study team, including submission to the NU IRB and the external IRB, as well as managing

communication between these offices. Furthermore, the NU's HRPP must have a current record of all research team personnel associated with the protocol. An updated research team form is to be submitted anytime a Northeastern investigator is added or removed from the study.

If the reliance request was initiated after the reviewing IRB approved the study, the addition of sites and/or collaborators will need to be specifically reviewed and approved, via a modification to the existing study.

Resources

CFR Title 45, Part 46

Engagement in Research: Office for Human Research Protection

NIH Single IRB Policy

HHS Single IRB Policy

SMART IRB